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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,372	01/15/2004	Herbert E. Schwartz	26502-73682	5422
23643 7590 10/13/2009 BARNES & THORNBURG LLP 11 SOUTH MERIDIAN 11 NDIANAPOLIS, IN 46204			EXAMINER	
			WOO, JULIAN W	
INDIANAPOL	.18, 1N 46204		ART UNIT	PAPER NUMBER
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			NOTIFICATION DATE	DELIVERY MODE
			10/13/2009	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

## Application No. Applicant(s) 10/758,372 SCHWARTZ ET AL. Office Action Summary Examiner Art Unit Julian W. Woo 3773 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 23 July 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-4 and 6-17 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-4 and 6-17 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTC/G5/08)
Paper No(s)/Mail Date \_\_\_\_\_\_

Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

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#### DETAILED ACTION

### Claim Rejections - 35 USC § 102

 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filled in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filled in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 35(1a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4 and 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Bonutti et al. (6,010,525). Bonutti et al. disclose, at least in figures 26-28 and col. 26, line 63 to col. 28, line 23; a device including a first anchor (540) having a locking mechanism (542) configured to grip and hold or lock a suture at any point along the suture; and a cannula (544) including a first lumen (578), the first anchor being shaped to seat below the first surface of soft tissue (54) or is capable of seating below the first surface of a meniscus, whereby proper seating of the device closes a defect without interfering with joint articulation; a second anchor (602) having a hole, and a suture (52), where the suture connects and first and second anchors by passing through the lumen of the cannula of the first anchor while traveling in a first direction, by passing through the hole of the second anchor, and by returning through the lumen of the cannula of the first anchor while traveling in a second and opposite direction, where tension on the suture pulls the second anchor toward the first anchor. Note: The introductory statement of intended use ("for repairing a defect in soft tissue" or a meniscus) has

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been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Bonutti et al., which is capable of being used as claimed if one desires to do so.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 4. Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti et al. (5,383,905) in view of Wilk (5,391,173). Bonutti et al. disclose the invention substantially as claimed, where the suture also forms a loop with respect to the first anchor, where the lumen of the first anchor includes a first opening (at 594) defined in a first side of the first anchor and a second opening (582 or 584) defined in a second side of the first anchor, the first opening larger than the second opening, and where the lumen of the first anchor is tapered (at 594). However, Bonutti et al. do

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not disclose that the first anchor has a frustoconical end shaped to bury into and seat below the first surface of the soft tissue. Wilk teaches, at least in figures 1, 2C, and 2D and in col. 3, line 66 to col. 4, line 2 and col. 4, lines 39-50; a suture anchor (8) including an external frustoconical shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Wilk, to modify the first anchor of Bonutti et al. so that it has a frustoconical shape or end-shape. Such a shape would provide a tapering surface for engagement of the anchor with a tool or by hand and allow sliding or pushing of the anchor along a suture and towards (or into) soft tissue.

# Response to Amendment

5. Applicant's arguments filed on July 23, 2009 and with respect to claims 1-4 and 6-17 have been fully considered but are not persuasive. With respect to arguments regarding the rejection of claims under 35 USC 102(e): Applicant alleges that the first anchor of Bonutti, deemed to be element 540 by the Examiner, is not "shaped to seat below the first surface of soft tissue (54)." Applicant is reminded that the recitation that an element is "shaped" to perform a function only requires the ability to so perform. And given the broadest reasonable interpretation of the phrase "below the first surface of soft tissue," Bonutti's first anchor is indeed capable of being seated or positioned below soft tissue, if, for example, the orientation of soft tissue, as shown in figure 26, is turned upside down, such that first anchor 540 is deemed to be "below" the first surface of soft tissue. Bonutti's recitation of the anchor being "pressed against an upper side surface 98 of body tissue" is only referring to an instance where the orientation of the body tissue as shown in figure 26 results in the suture retainer being above the first surface of

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tissue. Certainly, a patient and his or her soft tissue may be oriented in various positions, and Bonutti's first anchor is configured to be oriented and fastened in place according to the position of a surface of the soft tissue—a position that may be deemed "below the first surface of tissue."

With respect to arguments regarding the rejection of claims under 35 USC 103(a): The Examiner agrees with the Applicant in that Bonutti discloses the "flat circular bottom side" of suture retainer 540 engaged with soft tissue. However, as pointed out in the rejection, Bonutti does not disclose that the suture retainer has a "frustoconical end shaped to bury into and seat below the first surface of the soft tissue." Nevertheless, Wilk provides a teaching of a suture anchor (8) with a frustoconical end, where the broad, flat circular bottom side of the anchor is engaged with soft tissue (just like Bonutti's device). Contrary to the Applicant's suggestion, the Examiner did not contend that the narrow, circular side of Wilk's frustoconical anchor is engaged with the soft tissue. In short, there is no concentration of "force at a small area" if the suture retainer of Bonutti is modified to a frustoconical shape as taught by Wilk, since Bonutti and Wilk teach the large, bottom sides of their anchors being engaged with tissue, where the anchors are configured to be "below" tissue (as defined above) and embedded (i.e., buried) in soft tissue.

#### Conclusion

 THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). Application/Control Number: 10/758,372

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should Application/Control Number: 10/758,372 Page 7

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/ Primary Examiner, Art Unit 3773